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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,992	11/13/2001	Terry B.J. Kuo	JCLA8137	3468
7590		05/18/2004	EXAMINER	
J.C. Patents, Inc.		MACHUGA, JOSEPH S		
4 Venture, Suite 250		ART UNIT		
Irvine, CA 92618		PAPER NUMBER		
		3762		

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/990,992

Applicant(s)

KUO, TERRY B.J.

Examiner

Joseph S. Machuga

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. §133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

The proposed drawing corrections noted in the response of Feb 19, 2004 was not received. An additional copy is respectfully requested.

Applicant's arguments have been carefully considered but are not deemed persuasive. Taylor #5301679 discloses a system for analyzing heart sounds. The system included components for collecting, processing and analyzing the data. The Kuo et al (effect of Aging on Gender Difference in Neural Control of Heart) publication and Tsuji et al (the Framingham Heart Study) document both teach the advantages of collecting and analyzing the HRV parameters to provide a measure of the patients health. Therefore, there is clear motivation for modifying the Taylor device. Accordingly the rejection of pending claims 1-5, 8 and 17-19 is considered proper.

***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hearing instrument as recited in claim 3 and the personal computer, PDA and microchip recited in claims 5 and 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor #5301679 in view of Kuo et al (Effect of Aging on Gender Difference in Neural Control of Heart publication.)

Taylor discloses method and apparatus for analyzing heart sounds. The device includes a microphone (1), amplifier (3), spectrum analyzer having filters (7), peak detectors, A/D converter (9) and a computer (10) for processing the information. The device looks for abnormalities in the heart sound. As noted in column 5, lines 61-68 abnormal sounds such as third heart sound, fourth heart sound, systolic and diastolic murmurs, systolic ejection click, and variations in amplitude and frequency are abnormal sounds that can be associated with cardiac disease. Not disclosed by this reference is the analysis of the HRV value.

Kuo et al teach analyzing the HRV of an ECG signal based on frequency, time and non-linear logarithmic data. The data provides a functional indicator of the patients health, autonomic nervous system and cardiovascular disease.

Given this teaching, it would have been obvious to one of ordinary skill in the art to modify Taylor's medical device to analyze the HRV parameters as discussed in Kuo et al's document to provide a diagnostic tool that looks at these factors that effect the patients health.

Claims 1, 2, 4, 5, 8, 15, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor #5301679 in view of Tsuji et al (The Framingham Heart Study.)

Taylor discloses method and apparatus for analyzing heart sounds. The device includes a microphone (1), amplifier (3), spectrum analyzer having filters (7), peak detectors, A/D converter (9) and a computer (10) for processing the information. The device looks for abnormalities in the heart sound. As noted in column 5, lines 61-68 abnormal sounds such as third heart sound, fourth heart sound, systolic and diastolic murmurs, systolic ejection click, and variations in amplitude and frequency are abnormal sounds that can be associated with cardiac disease. Not disclosed by this reference is the analysis of the HRV value.

Tsuji et al teaches analyzing the HRV of an ECG signal based on frequency, time and non-linear logarithmic data as well as LF, HF, LF/HF the TP value to predict the outcome of a patient.

Given this teaching, it would have been obvious to one of ordinary skill in the art to modify Taylor's medical device to analyze the HRV parameters as discussed in Tsuji et al to provide a predictable tool for diagnosing the outcome of a patient.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Kuo et al or Taylor #5301679 in view of Tsuji et al (The Framingham Heart Study) as applied to claim 1 above, and further in view of either Eisenburg et al or Johnson et al.

Both Eisenburg and Johnson et al teach integrating the electronics of a heart analyzer into a stethoscope (instrument used in auscultation.) The devices would obviously add convenience to the practitioners.

Given there teaching it would have been obvious to one of ordinary skill in the art to incorporate the analyzer of the proposed combination into a stethoscope to add convenience for the practitioner.

Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Kuo et al as applied to claims 1, 2, 4, 5, 17, and 18 above, and further in view of Tsuji et al (The Framingham Heart Study.)

Tsuji et al teach analyzing the HRV data that includes in addition to the LF, HF, LF/HF values the TP value to predict the outcome of a patient.

Given this teaching it would have been obvious to one of ordinary skill in the art to include the total power (TP) value in the analysis of the heart data in the proposed combination to provide an indicator of the hearts strength.

### ***Conclusion***

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Joseph S. Machuga  
Examiner  
Art Unit 3762

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**ANGELA D SYKES**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**